I. AMENDMENTS TO THE CLAIMS

This listing of the claims will replace all prior versions and listings. Claims 1-28 have been canceled and new claims 29-56 have been added.

Listing of Claims:

Claims 1-28 canceled.

Claim 29 (New) A method of preventing hemophilic bleeding in advance of a bleeding event, said method comprising:

a) aerosolizing a monomeric Factor IX (FIX), wherein the aerosolized monomeric FIX: i) has a mass median aerodynamic diameter (MMAD) of between 2 and 4 μm, ii) has a fine particle fraction percent less than 3.3 μm (FPF %<3.3 μm) of at least 50%, iii) is at least 90% monomeric, iv) wherein the after-aerosolization activity/pre-aerosolization activity is at least 80%; and v) is a dry powder having less than 10% water (wt/wt), but does not have ethanol;

b) slowly maximally inhaling aerosolized monomeric FIX; and

c) allowing said monomeric FIX to deposit in the deep lung tissue such that said monomeric FIX is sequestered in said deep lung tissue to provide sufficient FIX to prevent bleeding for at least 100 hours after administration.

Claim 30 (New) The method of claim 29, wherein said FIX is inhaled biweekly.

Claim 31 (New) The method of claim 29, wherein said FIX is inhaled every 2 to 3 days.

Claim 32 (New) The method of claim 29, wherein said FIX is prepared by

a) diafiltering concentrated FIX solution to a concentration of approximately 12 mg/ml;

b) spray drying the diafiltered solution at approximately 50 psi between 60°C and 70°C at 5 ml/min and approximately 18 standard cubic feet per minute (scfm); and

c) transferring spray dried FIX to a sealed storage container at less than 5% humidity.

Claim 33 (New) A prophylactic method of treating hemophilia, said method comprising

a) aerosolizing a monomeric Factor IX (FIX), wherein the aerosolized monomeric FIX: i) has a mass median aerodynamic diameter (MMAD) of between 2 and 4 μm, ii) has a fine particle fraction percent less than 3.3 μm (FPF %<3.3 μm) of at least 50%, iii) is at least 90% monomeric, iv) wherein the after-aerosolization activity/pre-aerosolization activity is at least 80%; and v) is a dry powder having less than 10% water (wt/wt), but does not have ethanol;

b) slowly maximally inhaling aerosolized monomeric FIX;

c) allowing said monomeric FIX to deposit in the deep lung tissue, and

d) followed by exhalation, wherein said monomeric FIX is sequestered in said deep lung tissue to provide sufficient FIX to prevent bleeding for at least 100 hours after administration.

Claim 34 (New) The method of claim 33, wherein said FIX is inhaled biweekly.

Claim 35 (New) The method of claim 33, wherein said FIX is inhaled every 2 to 3 days.

Claim 36 (New) The method of claim 33, wherein said FIX is prepared by

a) diafiltering concentrated FIX solution to a concentration of approximately 12 mg/ml;

b) spray drying the diafiltered solution at approximately 50 psi between 60°C and 70°C at 5 ml/min and approximately 18 standard cubic feet per minute (scfm); and

c) transferring spray dried FIX to a sealed storage container at less than 5% humidity.

Claim 37 (New) A method of preventing hemophilic bleeding in advance of a hemophilic assault, said method comprising:

a) aerosolizing a Factor IX (FIX), wherein the aerosolized FIX: i) has a mass median aerodynamic diameter (MMAD) of between 2 and 4 μm, ii) has a fine particle fraction percent less than 3.3 μm (FPF %<3.3 μm) of at least 50%, iii) is at least 90% monomeric, iv) wherein the after-aerosolization activity/pre-aerosolization activity is at least 80%; and v) is a dry powder having less than 10% water (wt/wt);

b) inhaling the aerosolized FIX at least once per week and allowing the aerosolized FIX to deposit in the lung; and

c) followed by exhalation wherein said monomeric FIX is sequestered in said lung tissue to provide sufficient FIX to prevent bleeding for at least 100 hours after administration.

Claim 38 (New) The method of claim 37, wherein the inhalation is bi-weekly.

Claim 39 (New) The method of claim 37, wherein the inhalation is every 2 to 3 days.

Claim 40 (New) A prophylactic method of treating hemophilic bleeding, said method comprising:

a) aerosolizing a Factor IX (FIX), wherein the aerosolized FIX: i) has a mass median aerodynamic diameter (MMAD) of between 2 and 4 μm, ii) has a fine particle fraction percent less than 3.3 μm (FPF %<3.3 μm) of at least 50%, iii) is at least 90% monomeric, iv) wherein the after-aerosolization activity/pre-aerosolization activity is at least 80%; and v) is a dry powder having less than 10% water (wt/wt);

b) slowly maximally inhaling aerosolized monomeric FIX; and

c) allowing said monomeric FIX to deposit in the lung such that said monomeric FIX is sequestered in said lung to provide sufficient FIX to prevent bleeding for at least 100 hours after administration.

Claim 41 (New) The method of claim 40, wherein the inhalation is bi-weekly.

Claim 42 (New) The method of claim 40, wherein the inhalation is every 2 to 3 days.

Claim 43 (New) A blister pack containing FIX, wherein the blister pack is waterproof and contains FIX that is at least 90% monomeric and has less than 10% (wt/wt) water and a surface active di- or tri-peptide excipient, but does not have ethanol, wherein said FIX is prepared by

a) diafiltering concentrated FIX solution to a concentration of approximately 12 mg/ml;

b) spray drying the diafiltered solution at approximately 50 psi between 60°C and 70°C at 5 ml/min and approximately 18 standard cubic feet per minute (scfm); and

c) transferring spray dried FIX to a sealed blister pack at less than 5% humidity.

wherein the blister pack is waterproof and contains FIX that is at least 90% monomeric and has less than 10% (wt/wt) water, but does not have ethanol.

Claim 44 (New) The blister pack of claim 43, wherein the FIX is at least 95% monomeric and has less than 5% (wt/wt) water and the excipient is a dileucyl or a tri-leucine.

Claim 45 (New) The blister pack of claim 43, wherein the FIX is at least 97% monomeric and has less than 5% (wt/wt) water and the excipient is tri-leucine.

Claim 46 The blister pack of claim 43, wherein the FIX is recombinant FIX.

Claim 47 (New) A dry powder monomeric FIX composition comprising about 50 wt % glycosylated FIX, about 40 wt % tri-leucine and about 10 wt % buffer wherein said monomeric FIX is prepared by:

a) diafiltering concentrated FIX solution to a concentration of approximately 12 mg/ml;

b) spray drying the diafiltered solution at approximately 50 psi between 60°C and 70°C at 5 ml/min and approximately 18 standard cubic feet per minute (scfm); and

c) transferring spray dried FIX to a sealed storage container at less than 5% humidity.

Claim 48 (New) The dry powder monomeric FIX composition of claim 47, wherein the monomeric FIX has a mass median aerodynamic diameter (MMAD) of between 2 and 4 μm and has a fine particle fraction percent less than 3.3 μm (FPF %<3.3 μm) of at least 50%.

Claim 49 (New) The dry powder monomeric FIX composition of claim 47, wherein said sealed storage container is a blister-pack.

Claim 50 (New) A composition comprising dry, dispersible powder and a solid content of 40-60 wt % glycosylated FIX, 40-60 wt % tri-leucine and 0-10 wt % buffer wherein said monomeric FIX is prepared by:

a) diafiltering concentrated FIX solution to a concentration of approximately 12 mg/ml;

b) spray drying the diafiltered solution at approximately 50 psi between 60°C and 70°C at 5 ml/min and approximately 18 standard cubic feet per minute (scfm); and

c) transferring spray dried FIX to a sealed storage container at less than 5% humidity.

Claim 51 (New) The dry powder monomeric FIX composition of claim 50, wherein the monomeric FIX has a mass median aerodynamic diameter (MMAD) of between 2 and 4 μm and has a fine particle fraction percent less than 3.3 μm (FPF %<3.3 μm) of at least 50%.

Claim 52 (New) The dry powder monomeric FIX composition of claim 50, wherein said sealed storage container is a blister-pack.